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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,303	04/14/2000	Brian Haab	S99-066	9147

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1655	10

DATE MAILED: 12/12/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/550,303	HAAB ET AL.	
	Examiner	Art Unit	
	BJ Forman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 19-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior applications because the first paragraph of the specification does not recite the claimed priority to Application 08/688,488, filed 07/30/1996 and Provisional Application 60/129,449, filed 4/15/1999.

Appropriate correction is required.

Election/Restrictions

2. Applicant's election with traverse of Group II in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the language of Claim 10 recites that the array is produce by "a method utilizing an elongate capillary channel" by "tapping the tip of the dispensing device against the solid support at a defined position" and therefore, the product as claimed cannot be made by another and materially different process. The argument is not found persuasive because Claim 10 is drawn to a microarray of polypeptides and the claimed microarray comprises polypeptides positioned on a solid support at defined positions. The claimed microarray can be made by another and materially different process of making the product e.g. inkjet, pins and alternative tip devices. The courts have stated that even though product-by-process claims are defined by the process of making the end-product, patentability of the end-product does not depend on its method of production (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113). Therefore, because the claimed microarray is not limited to the method steps for recited in Claim 10 making the microarray, and because the microarray as claimed can be made by other and materially different processes, the requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 10-18 are indefinite in Claim 10, line 7 for the recitation "on the surface" because "surface" lacks proper antecedent basis in the claim. It is suggested that Claim 10 be amended to provide proper antecedent basis e.g. replace "the" with "a" and after "surface" insert "of the solid support".

b. Claims 10-18 are indefinite in Claim 10, line 7 for the recitation "to break the meniscus" because "meniscus" lacks proper antecedent basis in the claim. It is suggested that Claim 10 be amended to provide proper antecedent basis e.g. replace "the" with "a".

c. Claims 11-13 and 15-18 are each indefinite because they are drawn to the microarray of Claim 9 which is drawn to the method of Claim 1. It is suggested that Claims 10-13 and 15-18 be amended to depend from the microarray of Claim 10. For purposes of examination, Claims 10-13 and 15-18 are interpreted as being drawn to the microarray of Claim 10.

d. Claim 14 is indefinite for the recitation "said immunological receptors" because the recitation lacks proper antecedent basis in Claim 11. It is suggested that Claim 14 be amended to provide proper antecedent basis e.g. amend Claim 14 to depend from Claim 13.

e. Claim 16 is indefinite for the recitation "a cationic film capable of binding said polypeptide" because it is unclear whether the film binds the polypeptide. It is suggested that

Claim 16 be amended to clarify e.g. replace "capable of binding" with "which binds" (page 4, lines 27-29).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung et al. (U.S. Patent No. 5,143,854, issued 1 September 1992).

Regarding Claim 10, Pirrung et al. disclose a microarray of polypeptides deposited at defined positions on a solid support (Column 8, lines 17-33). The microarray of Pirrung et al. is made by another process. However, the courts have stated patentability of a product does not depend upon the process of making the product.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113).

Therefore, even though the microarray of Pirrung et al. is made by a process which differs from the claimed microarray, their end-product microarray is the same as the claimed microarray and therefore, Pirrung et al. disclose the claimed microarray.

Regarding Claims 11-13 and 15-18, as stated above, the claims are indefinite because they are drawn to the microarray of Claim 9 which is drawn to the method of Claim 1. For purposes of examination, Claims 10-13 and 15-18 are interpreted as being drawn to the microarray of Claim 10.

Regarding Claim 11, Pirrung et al. disclose the microarray comprising 100 or more discrete regions/cm^2 (Column 15, line 56-Column 16, line 1).

Regarding Claim 12, Pirrung et al. disclose the microarray comprising 1000 or more discrete regions/cm^2 (Column 15, line 56-Column 16, line 1).

Regarding Claim 13, Pirrung et al. disclose the microarray wherein the polypeptides are immunological receptors i.e. antibodies (Column 3, lines 54-58).

Regarding Claim 14, Pirrung et al. disclose the microarray wherein the polypeptides are antibodies (Column 3, lines 54-58).

Regarding Claim 17, Pirrung et al. disclose the microarray wherein the polypeptides are at least 50 amino acids in length (Column 9, lines 60-63).

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 15 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pirrung et al. (U.S. Patent No. 5,143,854, issued 1 Sept 1992).

Regarding Claim 15, Pirrung et al. disclose the microarray wherein the polypeptides are antigens i.e. the polypeptides on the array are screened for antibody interactions (Column 7, lines 8-17). The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Pirrung et al. is silent with regard to the antibody interacting polypeptide being antigens. However, the antigens recited in Claim 15 is deemed to be inherent in the antibody-binding polypeptides of Pirrung et al. because antibody-binding polypeptides are by definitions antigens. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-binding polypeptides taught by Pirrung et al. and to provide a microarray comprising antibody-binding antigens to thereby provide means for screening and/or selecting from antigen-specific antibodies for the expected benefit of vaccine development as taught by Pirrung et al. (Column 7, lines 8-17). The burden is on applicant to show that the claimed antigen is either different or non-obvious over that of Pirrung et al.

Regarding Claim 18, Pirrung et al. teach the microarray is useful for screening biological activity (Column 3, lines 39-61) which clearly suggests the polypeptides retain their native structure because screening of biological activity requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the screening would not determine biological activity. The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Pirrung et al. is silent with regard to native three-dimensional structure of the polypeptides. However, the native structure recited in Claim 18 is deemed to be inherent in the screening of biological activity in Pirrung et al. because absent native conditions e.g. three dimensional structure, screening would not determine biological activity as required in the teaching of Pirrung et al. Alternatively, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Pirrung et al. to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or

identify native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Pirrung et al.

Claim Rejections - 35 USC § 103

9. Claims 10-15, 17 and18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996).

Regarding Claim 10, Beattie teaches a microarray comprising binding reagents deposited at defined positions on a solid support (Claims 1 and 15) and they teach the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52). Additionally, they teach binding reagents include antibody-antigen and ligand-receptor binding (Column 7, lines 20-21) and are effective for carrying out immunochemical analysis of protein mixtures, epitope mapping, assay of receptor-ligand binding (Column 15). The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Beattie is silent with regard to binding reagent being a polypeptide. However, the polypeptide recited in Claim 10 is deemed to be inherent in the binding reagents in Beattie because their antigen-antibody and ligand-receptor binding reagents encompasses polypeptides which are effective for carrying out immunochemical analysis of protein mixtures, epitope mapping, assay of receptor-ligand binding all of which clearly suggests their microarray encompasses a microarray of polypeptides. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the suggested polypeptides of Beattie to their microarray to thereby obtain a microarray of polypeptides for the obvious benefit of providing means for characterizing and/or identifying a multiplicity of polypeptide-

binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3). The teaching of Beattie differs from the instantly claimed invention only in the process of making the microarray. However, the courts have stated patentability of a product does not depend upon the process of making the product.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113).

Therefore, because Beattie clearly suggests their microarray comprises polypeptides, the claimed microarray of polypeptides is obvious in view of the teaching of Beattie, even thought the microarray of Beattie is made by a different process.

Regarding Claims 11-13 and 15-18, as stated above, the claims are indefinite because they are drawn to the microarray of Claim 9 which is drawn to the method of Claim 1. For purposes of examination, Claims 10-13 and 15-18 are interpreted as being drawn to the microarray of Claim 10.

Regarding Claim 11, Beattie teaches the microarray comprises 100 or more discrete regions/cm^2 (Column 5, line 66-Column 6, line 6).

Regarding Claim 12, Beattie teaches the microarray comprises 1000 or more discrete regions/cm^2 (Column 5, line 66-Column 6, line 6).

Regarding Claim 13, Beattie teaches the microarray wherein the binding reagents include antibody-antigen binding (Column 7, lines 20-21) and are effective for carrying out immunochemical analysis of protein mixtures and receptor-ligand binding (Column 15). The claim is given the broadest reasonable interpretation consistent with the claim language and specification wherein "immunological receptors" are not defined. Therefore, because the

antibody-antigen binding and immunochemical analysis of Beattie encompasses immunological receptors, Beattie teaches the claimed immunological receptors.

Regarding Claim 14, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antibodies (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antibodies. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antibodies as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antibody-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identifying clinically important antibody-binding reagents.

Regarding Claim 15, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 17, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antibodies and it was well known in the art that antibodies comprises at least 50 amino acids (Column 7, lines 20-21) but the do not specifically teach their binding reagents comprise at least 50 amino acids. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie

and to provide a microarray comprising antibodies as suggested by Beattie which are know to comprise at least 50 amino acids, to thereby provide means for characterizing and/or identifying a multiplicity of antibody-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identifying clinically important antibody-binding reagents.

Regarding Claim 18, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as applied to Claim 10 above and further in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claim 16, Beattie teaches a microarray comprising binding reagents deposited at defined positions on a solid support (Claims 1 and 15) and they teach the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52) but they do not teach a cationic film on the solid support capable of binding said polypeptide. However,

cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Beattie and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (U.S. Patent No. 5,142,854, issued 1 September 1992) in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claim 16, Pirrung et al. teach a microarray of polypeptides deposited at defined positions on a solid support (Column 8, lines 17-33) but they do not teach a cationic film on the solid support capable of binding said polypeptide. However, cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Pirrung et al. and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1655
December 10, 2001